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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,874	03/20/2006	Sakae Tsuda	19758-002US1-OSP-18668	7504

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FISH & RICHARDSON P.C. (BO)
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT	PAPER NUMBER
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1656

NOTIFICATION DATE	DELIVERY MODE
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09/27/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/549,874	Applicant(s) TSUDA ET AL.	
	Examiner KAGNEW H. GEBREYESUS	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-3 and 7-11 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-3 and 7-11 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 14, 2011 has been entered. Claim 1 is amended. Claims 10 and 11 are new. Claims 1-3, 7-11 are present for examination.

Objections and rejections not re-iterated from the previous action are hereby withdrawn.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by or in the alternative, under 35 U.S.C. 103(a) as obvious over Fenn et al (WO/1998/004147 published in May 02, 1998 in IDS) in view of Chao et al (Structure-function relationship in the globular type

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III antifreeze protein: Identification of a cluster of surface residues required for binding to ice.

Protein Science Vol. 3, 10, pages 1760-1769, 1994) further in view of Tong et al.

Applicants argue:

“...Independent claim 1, as amended, recites "deriving an antifreeze protein from fish without heat treatment." Neither Fenn nor Chao, whether taken alone, or in any proper combination, describes such features. Although Fenn mentions "fish AFPs" in the background discussion, Fenn does not describe deriving an antifreeze protein from fish, let alone deriving the antifreeze protein without heat treatment. Instead, Fenn isolates anti-freeze peptides from plants including winter-rye and grass by boiling or heating to 85 °C to 100 °C (page 11, lines 4-5 and 16-17, and page 12, lines 4-4 and 12-14)...”

Applicant’s arguments have been carefully considered but the argument has not been found persuasive. In the first instance the claims are drawn to method of using a fish derived AFP with any sequence (since the claims do not specify any sequence of any AFP). Thus a chimeric AFP with only a few amino acids from fish AFP III would be within the limitation of “fish derived AFP” in the instant claims. It should also be noted that Applicants claim is not drawn to a method of isolating a specific fish AFP wherein the isolation is done without heat treatment. Applicants claims are drawn to a method of using any AFP sequence derived from fish wherein said AFP is used to inhibit freeze concentration of a substance other than water molecules contained in a hydrous material.

Applicants acknowledge that both Fenn and Chao teach that the AFP used in their method can be derived from fish. Specifically on page 6, line 36 of Fenn teaches that fish as a source of AFP, on page 7 line 30-31 Fenn states: "For the purpose of the invention preferred AFP are derived from fish...”.

Furthermore Fenn teaches that AFP can be obtained through genetic modification i.e. a gene construct comprising AFP from any source including AFP from fish which can be expressed in host cells such as microorganisms. Furthermore they teach isolation and purification of the recombinant AFP that does not require heat treatment (especially isolated from microorganisms). Moreover at the time of the instant invention the art of recombinant technology for production of large amounts of desired proteins was well known.

Furthermore with regards to isolation of antifreeze polypeptides expressed and purified without heat treatment, the art for example Tong et al (Extracellular Expression, Purification, and Characterization of Winter flounder Antifreeze Polypeptide from *Escherichia coli* --Protein Expression and purification 18, 175-181 (2000)) teach expressing AFP from Winter flounder and expressing the same in *Escherichia coli*, wherein the purification does not require heat treatment.

Therefore, the skilled artisan could have used any of the possible AFP polypeptides available at the time of the instant invention – for example such as those disclosed by Fenn et al or by Tong et al. Thus the limitation of a method that uses “fish AFP isolated without heat treatment” is within the limitation of the disclosure by Fenn et al thus is anticipated or in the alternative the limitation is *prima facie* obvious over the disclosure of Fenn et al and Tong et al.

Applicants further argue:

On the other hand, although Chao recognizes that fish can have antifreeze proteins (page 1760, last paragraph in the right column), Chao does not describe deriving an antifreeze protein from fish. Instead, Chao produces antifreeze proteins from *E. coli* and refers to a reference "Use of proline mutants to help solve the NMR solution structure of type III antifreeze protein" by Chao et al., ("Chao 1993," a copy of which is submitted herewith). Chao 1993 describes that an insoluble AFP is extracted as inclusion bodies from *E. coli* sonicate pellet (page 1426, left column, lines 1-2). Although Chao 1993 analyzes antifreeze protein from ocean pout, Chao 1993 does not describe deriving the protein from the ocean pout and is silent regarding "deriving an antifreeze protein from fish without heat treatment." For production of the antifreeze protein from ocean pout, Chao 1993 refers to a reference "Structure of an antifreeze polypeptide and its

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precursor from the ocean pout, *Macrozoarces americanus*", by Li et al, J. Biol. Chem. 260, 12902-12909 (page 1426 of Chao 1993, second paragraph in the left column)".

Applicant's argument has been carefully considered but not found persuasive. Fenn et al is discussed above. Furthermore as acknowledged by Applicants, Chao et al do teach AFP isolated from fish (ocean pout). Furthermore while the AFP was expressed and purified from *E. coli*, the nucleic acid encoding the recombinant AFP protein was derived from fish (ocean pout, *Macrozoarces americanus*) rQAE) were said AFP was found to have wild type antifreeze activity (see page 1761 second paragraph under sub-title 'Results'). Furthermore Chao (1994) refers to Li et al's study as one of the source of "fish AFP". Examination of the Li et al reference, teaches isolation, purification and characterization of a *Macrozoarces americanus* (fish) AFP including sequencing the AFP. The reference does not hint on the use of heat for isolation of the AFP III.

Moreover Chao et al disclose the sequence of the recombinant synthetic AFP type III derived from fish in fig. 1. In addition while heat induction was used for increasing the expression of the AFP from *E. coli*, heat treatment was clearly not required for antifreeze activity *per se* (see for example page 1412, column 2 under Results and fig. 2). This is because the pT7-7 vector used to express AFP III comprises the T7 RNA polymerase gene that is under the control of a heat inducible *E. coli* promoter (pT7-7) (This vector was only required for expression of the recombinant AFP).

In the alternative even if one was to assume heat induction as a claim limitation, the art is replete with disclosures that teach recombinant expression of desired proteins that do not require

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heat induction. For example one of ordinary skill in the art can clone the AFP III gene under the control of any other inducible promoter such as for example a *lac* promoter that is induced by IPTG and express the AFP in view of using the same in the claimed method. Thus the mode of expressing the AFP would have been a simple substitution of one promoter for another and would have been well within the prevue of the ordinary skill in the art. Claims 10 and 11 are included in this rejection because the AFP taught by Chao, Tong et al and Li et al. is type III AFP proteins.

Furthermore while the concentration of an AFP protein of at least 0.02% (claim 1) or between the range 0.03% to 0.05% by weight with respect to the weight of hydrous material (in claim 11) is not specifically recited, Chao et al (1994) teach a curve (see fig. 4) wherein increasing activity of AFP III is shown with increasing concentration of AFP III. Thus the optimum concentration of AFP to use for the purpose of inhibiting freeze concentration would have been a matter of optimization which is well within the prevue of the ordinary skill in the art.

It should be noted that in KSR, the Supreme Court particularly emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. "[I]n *Sakraida v. AG Pro, Inc.*, the Court derived ... the conclusion that when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious."

Therefore it would have been obvious to decipher the minimum concentration of AFP III (claim 1) or to decipher the optimum range of AFP III concentration to use as disclosed in claim 11. Thus, the instant claims are unpatentable because the claims are anticipated or in the

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alternative, *prima facie* obvious over the teachings of Fenn et al, Tong et al in view of Chao et al, and Li et al.

Conclusion: No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAGNEW H. GEBREYESUS whose telephone number is (571)272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MANJUNATH RAO can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAGNEW H GEBREYESUS/
Primary Examiner, Art Unit 1656
September 19, 2011.

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